

K090773

JUN 23 2010

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## 510(k) SUMMARY

### Kai Medical Non-Contact Respiratory Rate Spot Check Model KMS 200

#### **Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

Kai Medical, Inc.  
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Honolulu, Hawaii 96816 USA

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Contact Person: Robert Nakata

Date Prepared: March 2, 2010

#### **Name of Device**

The Kai Medical Non-Contact Respiratory Rate Spot Check Model KMS 200 ("Kai Spot KMS 200")

#### **Common or Usual Name**

Respiratory Rate Spot Check

#### **Classification Name**

Breathing Frequency Monitor

#### **Predicate Devices**

The Kai Medical Non-Contact Respiratory Rate Spot Check Model KMS 200 ("Kai Spot KMS 200") is substantially equivalent to the Kai Medical Non-Contact Respiratory Rate Spot Check Model 100 ("Kai RSpot 100", 510(k) Number: K090273).

#### **Device Description**

The sensor includes a 2.4 GHz Doppler radar, data acquisition circuitry, processing, user interface, and touch-screen display. The touch-screen display provides the display and user interface. The device is powered over the USB connection, either by a PC, with a wall-power adapter, or with an external battery. If desired, the Kai Spot KMS 200 has the capability to communicate via its USB interface with a personal computer (PC) using select Kai Spot data

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management software applications. The sensor uses Doppler radar to detect respiratory effort, and the respiratory effort signal is analyzed to provide a respiratory rate. A radio wave in the 2.4 GHz ISM band is emitted from the antenna included in the hardware module. The Kai Spot KMS 200 sensor enclosure includes screw holes in a VESA mounting pattern (VESA is a standard mounting configuration), which can be used to connect to any VESA mount, including stands, carts, wall-mounts, or adapters to other stands or carts. A stand is not included with the device; the customer's Biomedical Engineering Department or maintenance service should install the device on a medical-grade stand used for vital signs measurement equipment. Screws to be used for mounting are provided with the device.

### **Physical Characteristics**

Dimensions of the Kai Spot KMS 200 Sensor Unit: 7.5" X 7.5" X 2"

Weight of the Kai Spot KMS 200 Sensor Unit: 1.2 lb

### **Performance**

Detectable Respiratory rate range: 8 to 48 breaths/minute

Accuracy:  $\pm 2$  breaths/minute

Resolution: 0.5 breath/minute

Range between sensor and subject: 0.2 to 1 meter

### **Operational Modes**

Measurement Duration: 30, 60, 120(3b) sec

3b mode: calculates rate for 3 consecutive breaths within 2 minute period

### **Power**

Power Input: USB type B

Power Requirements: USB powered (5V, <500mA)

Power Consumption: Less than 500 mA at 5V

### **Communications**

#### USB 2.0

- Start/Stop measurement
- Aiming light on/off
- Respiration rate in breaths/minute
- Retry/Error with code for type of Retry/Error
- Sensor status feedback

### **Radio Specifications**

Radio frequencies: 2.435 to 2.465 GHz

Radio power (EIRP): Less than 18dBm

Signal Bandwidth: Less than 2MHz

Modulation: Psuedo Random Phase modulation

Antenna gain: 13 dBi

## Features

Aiming Light: 8° viewing angle illuminating area of measurement

### OLED Touch Screen Display

Diagonal Size; 2.83"  
 Resolution; 240 x RGB x 320  
 Pixel Pitch; 0.060 × 0.180 mm  
 Active Area; 43.2 x 57.6 mm  
 Outline Area; 49.1 x 67.3 mm  
 Thickness; 1.75 (Typ) ; 1.95 (Max) mm

### Speaker

Impedance: 8  $\Omega$   $\pm$ 15%  
 Rated power: 0.75 W  
 Maximum power: 1.10 W  
 Resonant frequency: 620  $\pm$ 20% Hz  
 Frequency range: 240 Hz – 20KHz

## Intended Use / Indications for Use

The Kai Medical Non-Contact Respiratory Rate Spot Check Model KMS 200 is intended for a one-time measurement of respiratory rate, as part of a vital signs assessment. The device is indicated for hospital or clinical use in adult patients. The device is intended to be operated by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

The Kai Medical Non-Contact Respiratory Rate Spot Check Model KMS 200 is not intended to monitor vital signs. This device is not an apnea monitor

## Technological Characteristics

The Kai Spot KMS 200 is a reusable sensor for measuring respiratory rate during vital sign assessments. The Kai Spot KMS 200 uses a low-power radar to sense chest displacement in order to obtain a respiratory rate. When the Kai Spot KMS 200 is operating and facing a patient, the Doppler radar transmits a low-power radio-frequency signal and receives the signal after it has reflected off the patient's torso. The receiver detects a phase shift on the signal due to chest displacement and converts this phase shift into a voltage that is digitized and processed with software, which determines a respiratory rate from the chest motion (respiratory effort) signal. A touch-screen provides the display and user interface for the device. The Kai Spot KMS 200 may communicate over USB with a personal computer (PC) using select Kai Spot data management software applications. The Kai Spot KMS 200 may operate on wall power, USB power from a PC, or power from an external battery.

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### **Performance Data**

The bench performance data demonstrates that the Kai Spot KMS 200 is as safe and effective as the Kai RSpot 100. Bench performance data further demonstrates that the Kai Spot KMS 200 operates within its specifications, including accuracy over the range of measured respiratory rates.

Because the Kai Spot KMS 200 does not contact the patient, there is no risk of inadvertent exposure to electric current, and there are no patient-contacting materials that could cause allergic reactions or skin sensitivity. The radio signals emitted by the Kai Spot KMS 200 are at a power well below that emitted by many consumer wireless devices and many medical devices.

### **Substantial Equivalence**

The Kai Spot KMS 200 has the same intended use, indications, and principles of operation as its predicate device, the Kai RSpot 100, and similar technological characteristics. The minor technological differences between the Kai Spot KMS 200 and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrates that the Kai Spot KMS 200 is as safe and effective as the Kai RSpot 100. Thus, the Kai Spot KMS 200 is substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Mr. Robert Nakata  
Chief Technology Officer  
Kai Sensors, Incorporated  
3465 Waialae Avenue, Suite 370  
Honolulu, Hawaii 96816

JUN 23 2010

Re: K100773

Trade/Device Name: The Kai Sensors Non-Contact Respiratory Rate Spot Check  
Model 200

Regulation Number: 21 CFR 868.1400

Regulation Name: Carbon Dioxide Gas Analyzer

Regulatory Class: II

Product Code: CCK

Dated: May 20, 2010

Received: May 24, 2010

Dear Mr. Nakata:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

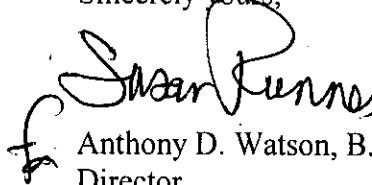
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson", is written over a circular stamp. The stamp contains the text "Anthony D. Watson, B.S., M.S., M.B.A. Director" and is partially obscured by the signature.

Anthony D. Watson, B.S., M.S., M.B.A.  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K090273

Device Name: The Kai Sensors Non-Contact Respiratory Rate Spot Check Model 200

## Indications for Use:

The Kai Sensors Non-Contact Respiratory Rate Spot Check Model 200 is intended for a one-time measurement of respiratory rate as part of a vital signs assessment. The device is indicated for hospital or clinical use in adult patients. The device is intended to be operated by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

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L. Schutt  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K100773

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)